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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,510	03/06/2001	Brett Cowan	3652-33	1367

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EXAMINER

LU, TOM Y

ART UNIT	PAPER NUMBER
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2621

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/786,510

Applicant(s)

COWAN ET AL.

Examiner

Tom Y Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Amendment*

1. The amendment and written response filed on April 20, 2004 has been considered.
2. Claims 1-37 are cancelled.
3. Claims 77-81 are newly added.
4. Claims 38-81 are pending.

### *Response to Arguments*

5. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 38-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheehan et al (U.S. Patent No. 6,106,466).

- a. Referring to Claim 38, Sheehan discloses defining the spatial position of at least two of the images (Sheehan at column 8, lines 64-66, teaches “the time varying position and orientation of the ultrasound transducer relative to magnetic field generator 68 comprise data that are stored in a non-volatile memory”, such

position data is spatial position data, which defines the position of the ultrasound transducer at the time each image frame is recorded by the CPU and thereby enable the CPU to compute the three-dimensional coordinates, column 9, lines 3-7); forming an initial fit between a reference model (Sheehan at column 12, line 9, discloses a mesh model of an archetype heart, which is the claimed “reference model”. Note Sheehan at column 13, line 3-6, teaches abstract mesh model is used for initial fitting) of the geometric shape of the organ or part thereof and the images according to reference markers on the images (column 13, lines 8-9, anatomic landmarks are the claimed “reference markers”); manually user-defining one or more reference guide points associated with one or more images displayed to a user, for which the spatial positions have been defined; converting the guide points to three-dimensional coordinates (Sheehan at column 11, lines 63-67, column 12, lines 1-2, teaches points of landmarks or structures are converted from x,y coordinates to x,y,z coordinates. Note points of landmarks or structures on observed images are the claimed “reference guide points”); improving the fit of the model by fitting the model to the guide points to form an estimate model for the organ or part (Sheehan at column 12, lines 53-61, teaches by reiteratively repositioning the control vertices or points to smooth the model to achieve the best fit. Note such control vertices are in association with anatomic landmarks. And these control vertices or points are the claimed “guide points”. Also see column 13, lines 11-12); and assessing the one or more characteristic from the

estimate model (the claimed “characteristics” herein are ventricular volume, mass, and function, ejection fraction, wall thickening, etc, column 17, lines 45-47).

- b. Referring to Claim 39, Sheehan discloses forming the initial fit between the reference model and the images by defining a point on each of two images, defining a reference line in 3-dimensional space between the point, calculating the distance as a function of the length of the reference line, and at least approximately matching the scale of the reference model and the images according to the distance between the points (Sheehan in figure 13, block 230, teaches mesh model rigidly aligned and scaled to match image data at 3 landmark points, and see the central axis in figure 6 for so-called “reference line”).
- c. Referring to Claim 40, Sheehan discloses wherein the reference model comprises a mathematically defined reference model (Sheehan at column 12, lines 8-11, teaches the reference model is a mathematically defined reference model).
- d. Referring to Claim 41, Sheehan discloses wherein the reference model comprises an ellipsoid having the reference line as a central axis and one or more surface points, each surface point specified by a radial distance from the central axis (see figure 6).
- e. Referring to Claim 42, Sheehan discloses the steps of displaying one or more images to a user and superimposing on the image a representation of the intersection of the reference model with the image (see figure 12).
- f. Referring to Claim 43, Sheehan discloses the step of performing image processing on one or more of the images (column 14, lines 64-66).

- g. Referring to Claim 44, Sheehan discloses wherein the reference points are boundary points on the image (column 13, lines 25-28).
- h. Referring to Claim 45, Sheehan discloses the step of calculating the volume of the subject organ or part from the estimate model (column 17, lines 45-47).
- i. Referring to Claim 46, Sheehan discloses the step of calculating the mass of the subject organ or part from the estimate model (column 17, lines 45-47).
- j. Referring to Claim 47, Sheehan discloses wherein the subject organ comprises a ventricle of the heart and the characteristics measured include ventricular mass, endocardial volume and/or wall thickness of all of the ventricle or part thereof (column 17, lines 45-47).
- k. Referring to Claim 48, Sheehan discloses wherein the subject organ comprises a ventricle of the heart and the characteristics measured include ventricular abnormalities identified through changes in a wall thickness over time (Sheehan at abstract teaches the imaging processing is carried out over at least one cardiac cycle, which allows user to define any ventricular abnormalities identified through changes in wall thickness over time).
- l. Referring to Claim 49, Sheehan discloses wherein the subject organ comprises a kidney and the characteristics measured included cortical thickness (Sheehan at column 9, lines 35-36, teaches his system is applicable to other organs in the patient's body, and a kidney is an organ).
- m. With regard to Claim 50, all limitations are addressed in Claim 38.
- n. With regard to Claim 51, all limitations are addressed in Claim 39.

- o. With regard to Claim 52, all limitations are addressed in Claim 40.
- p. With regard to Claim 53, all limitations are addressed in Claim 41.
- q. With regard to Claim 54, all limitations are addressed in Claim 42.
- r. With regard to Claim 55, all limitations are addressed in Claim 43.
- s. With regard to Claim 56, all limitations are addressed in Claim 44.
- t. With regard to Claim 57, all limitations are addressed in Claim 45.
- u. With regard to Claim 58, all limitations are addressed in Claim 46.
- v. With regard to Claim 59, all limitations are addressed in Claim 47.
- w. With regard to Claim 60, all limitations are addressed in Claim 48.
- x. With regard to Claim 61, all limitations are addressed in Claim 49.
- y. With regard to Claim 62, the only difference between Claim 62 and Claim 38 is  
Claim 62 calls for a computer program, Sheehan at column 8, line 15, teaches a  
software running on CPU 52 to carry out all the implementation steps.
- z. With regard to Claim 63, all limitations are addressed in Claim 39.
- aa. With regard to Claim 64, all limitations are addressed in Claim 40.
- bb. With regard to Claim 65, all limitations are addressed in Claim 41.
- cc. With regard to Claim 66, all limitations are addressed in Claim 42.
- dd. With regard to Claim 67, all limitations are addressed in Claim 43.
- ee. With regard to Claim 68, all limitations are addressed in Claim 44.
- ff. With regard to Claim 69, all limitations are addressed in Claim 45.
- gg. With regard to Claim 70, all limitations are addressed in Claim 46.
- hh. With regard to Claim 71, all limitations are addressed in Claim 47.

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- ii. With regard to Claim 72, all limitations are addressed in Claim 48.
- jj. With regard to Claim 73, all limitations are addressed in Claim 49.
- kk. Referring to Claim 74, Sheen at column 8, line 68, discloses non-volatile memory such as a hard drive, which is a computer readable medium.
- ll. With regard to Claim 75, all limitations are addressed in Claim 38.
- mm. With regard to Claim 76, all limitations are addressed in Claim 39.
- nn. With regard to Claim 77, the only difference between Claim 77 and Claim 38 is Claim 77 calls for additional limitation of “displaying one or more images to a user and superimposing on the image a representation of the intersection of the reference model with the image, which Sheehan in figure 13, block 230, teaches aligning mesh model to match image data at 3 landmark points. Aligning a mesh model on the image data is the claimed “superimposing the reference model on the image”, and a mesh model is the claimed “a presentation of the intersection of the reference model” as shown in figures 6 and 8, and such alignment process is displayed on a graphic display 54.
- oo. With regard to Claim 78, all limitations are addressed in Claim 39.
- pp. With regard to Claim 79, all limitations are addressed in Claim 39.
- qq. With regard to Claim 80, all limitations are addressed in Claim 40.
- rr. With regard to Claim 81, all limitations are addressed in Claim 44.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



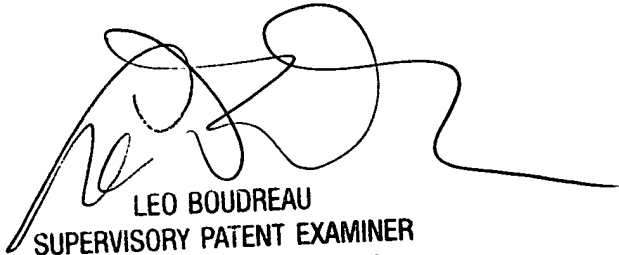
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tom Y Lu whose telephone number is (703) 306-4057. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tom Y. Lu



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